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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,669	05/25/2000	Kenneth H. Grabstein	2831-E	7760

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/578,669

Applicant(s)

Grabstein et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 6, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-55 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 26-55 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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***Election/Restriction***

Applicant's amendment filed November 6, 2001 (Paper Number 6) has been received and entered. Claims 1-2, 20 and 23-25 have been canceled, and new claims 26-55 have been inserted. Consequently claims 26-55 are pending in the instant application. In view of Applicant's newly added claims the following new restriction is being made:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
    - I. Claims 26-29, 35-38, 40-41, 43-44 and 46, drawn to antagonists comprising IL-15 conjugated with a chemical group, classified in class 530, subclass 350.
    - II. Claims 26, 30-37, 39-41, 43, and 45-46, drawn to antagonists comprising a mutein of IL-15 conjugated with a chemical group, classified in class 530, subclass 350.
    - III. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of organ transplant rejection or graft versus host disease, classified in class 424, subclass 193.1.
    - IV. Claim 47, 52, 54, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of organ transplant rejection or graft versus host disease classified in class 424, subclass 193.1.
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- V. Claim 47, 53-54, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of autoimmune disease, classified in class 424, subclass 193.1.
  - VI. Claim 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of autoimmune disease classified in class 424, subclass 193.1.
  - VII. Claims 47-49, 51, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of rheumatoid arthritis, classified in class 424, subclass 193.1.
  - VIII. Claims 47-48, 50-51, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of rheumatoid arthritis classified in class 424, subclass 193.1.
  - IX. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of inflammatory bowel disease, classified in class 424, subclass 193.1.
  - X. Claim 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of inflammatory bowel disease classified in class 424, subclass 193.1.
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- XI. Claims 47-49, 51, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of lymphoma, classified in class 424, subclass 193.1.
  - XII. Claims 47-48, 51, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of lymphoma, classified in class 424, subclass 193.1.
  - XIII. Claims 47-49, 51, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of carcinoma, classified in class 424, subclass 193.1.
  - XIV. Claims 47-48, 50-51, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of carcinoma, classified in class 424, subclass 193.1.
  - XV. Claims 47-49, 51, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of leukemia, classified in class 424, subclass 193.1.
  - XVI. Claims 47-48, 50-51, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of leukemia, classified in class 424, subclass 193.1.
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- XVII. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of rhabdosarcoma, classified in class 424, subclass 193.1.
  - XVIII. Claims 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of rhabdosarcoma, classified in class 424, subclass 193.1.
  - XIX. Claims 47-49, 51, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of a dermatological disorder, classified in class 424, subclass 193.1.
  - XX. Claims 47-48, 50-51, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of a dermatological disorder, classified in class 424, subclass 193.1.
  - XXI. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of Type I diabetes, classified in class 424, subclass 193.1.
  - XXII. Claim 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of Type I diabetes, classified in class 424, subclass 193.1.
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- XXIII. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of an ocular disorder, classified in class 424, subclass 193.1.
- XXIV. Claim 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of an ocular disorder, classified in class 424, subclass 193.1.
- XXV. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of idiopathic nephrotic syndrome, classified in class 424, subclass 193.1.
- XXVI. Claim 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of idiopathic nephrotic syndrome, classified in class 424, subclass 193.1.
- XXVII. Claim 47, drawn to methods of treatment with IL-15 conjugated to a chemical group to a patient having symptoms of idiopathic membranous nephropathy, classified in class 424, subclass 193.1.
- XXVIII. Claim 47, drawn to methods of treatment with a mutein of IL-15 conjugated to a chemical group to a patient having symptoms of idiopathic membranous nephropathy, classified in class 424, subclass 193.1.
- XXIX. Claim 55, drawn to a method for making an antagonist with IL-15 conjugated to a chemical group, classified in class 435, subclass 68.1.
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XXX. Claim 55, drawn to a method for making an antagonist with an IL-15 mutein conjugated to a chemical group, classified in class 435, subclass 68.1.

Additionally, Groups I-XXX are further restricted according to MPEP 823.04 which sets forth that biological molecules having different sequences are considered distinct inventions. Accordingly, Applicant is restricted to a single sequence including recited substitutions (i.e., SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 2 in which asp 56 is substituted with serine; SEQ ID NO: 2 in which asp 56 is substituted with cysteine; SEQ ID NO: 2 in which Gln 156 is substituted with serine; or SEQ ID NO: 2 in which Gln 156 is substituted with cysteine).

2. The inventions are distinct, each from the other because of the following reasons:

Invention I, drawn to antagonists comprising IL-15 conjugated to a chemical group is distinct from Invention II, drawn to antagonists comprising a mutein of IL-15 conjugated to a chemical group, since the primary, secondary, and tertiary structure of the molecule is altered, thereby resulting in a separate search of different molecules.

Inventions III-XXVIII each drawn to a method of treatment with either IL-15 conjugated to a chemical group, or a mutein of IL-15 conjugated to a chemical group is distinct from each other since each group requires the selection of individuals displaying different symptoms, and each of the recited groups has a separate etiological agent as well as standard methods of therapy.

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Inventions XXIX & XXX and I & II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to generate conjugated molecules with different activities and structure (e.g., IL-2, IL-5 etc.).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.



Mark Navarro

Primary Examiner

January 31, 2002

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